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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/526,768	11/07/2005	Enno Klussmann	Gulde-0058	6937

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EXAMINER	
SWOPE, SHERIDAN	

ART UNIT	PAPER NUMBER
1652	

MAIL DATE	DELIVERY MODE
11/06/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/526,768	KLUSSMANN ET AL.	
	Examiner	Art Unit	
	Sheridan L. Swope	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 July 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) *6-8 and 11-17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,9 and 10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *07 March 2005* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *0305*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's election with traverse of Invention I in their response of July 25, 2007 is acknowledged. The elected invention is directed to a polynucleotide encoding a kinase polypeptide. Applicants' traversal is based on the following arguments.

(A) The requirement for an election of species for Inventions III-V is rendered moot by Applicants' election of Invention I.

(B) The special technical feature linking all claims is, for example, a polynucleotide that encodes a kinase, as recited in Group I. The Examiner gives no explanation as to why Trotter et al, 1999 overcomes the unity of invention.

(C) If examination of the complete application can be made without a burden, it must be examined.

(D) At a minimum, Groups IV and V should be combined.

(A) Reply: It is acknowledged that, since Applicants have elected Invention I, they are not required to elect any one of species (A)-(Q), which are relevant only to Inventions III-V.

(B) Reply: Since all claims do not recite polynucleotides, or methods of making or using polynucleotides, a polynucleotide that encodes a kinase cannot be a special technical feature. As explained in the prior action, the technical feature linking all claims is that they all relate to kinase polypeptides. However, kinase polypeptides were known in the art. As also explained in the prior action, Trotter et al, 1999 teach a kinase polypeptide that has 69% homology to SEQ ID NO: 1 and comprises more than two contiguous nucleotides of SEQ ID NO: 1, which anticipates Claim 1. Therefore Groups I-V share no special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art.

(C) Reply: As explained in the prior action, because the products of Groups I-III do not share a special structural and functional feature, a search for any one said product would not encompass a search for any other said products and searching more than one product would be a burden on the Office. Likewise, a search for the method of Group IV or V would not encompass a search for the other said method because the methods do not share a special technical feature of steps and products used, and results produced. Since a search of any one of the products of Groups I-III would not encompass a search of any of the methods of Groups IV and V, or vice versa, and because said methods are not the only methods of making or using said products, a search for any of said products with any said methods would be a burden on the Office.

(D) Reply: As explained in the prior action, should applicant traverse on the ground that inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-17 are pending. Claims 6-8 and 11-17 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim. Claims 9 and 10, in part, and Claims 1-5 are hereby examined.

It is noted that Claim 12 is incorrectly labeled as a second Claim 11.

Priority

The priority date granted for the instant invention is February 7, 2003, the filing date of DE 103-06-085, which disclosed the elected invention. If Applicants wish to perfect their priority claim to DE 102-44-072, an English translation thereof should be filed.

Oath

The Oath is objected to because the filing dated listed for PCT/EP03/009892, March 7, 2005, is incorrect. According to WIPO, the filing date for said application is September 5, 2003.

Sequence Listing

The sequence listing annotates SEQ ID NO: 1 as a human protein. However, GenEMBL annotates SEQ ID NO: 1 as a rat protein (Accession no. AY350741/GI:37993505). Clarification is required.

Information Disclosure Statement

The Information Disclosure Statement lists reference #001 by Klussmann et al, 2000. Said reference has not been considered because it has not been supplied by Applicants and the Examiner is not able to locate it. If Applicants wish for said reference to be considered, a supplemental Information Disclosure Statement, the reference, and an English language translation of the reference should be submitted. Any subsequent rejection, based on consideration of the supplemental Information Disclosure Statement, will not be considered new grounds for rejection.

Drawings

The drawings are objected to for disclosing sequences that are not identified by a sequence identifier number (SEQ ID NO:). The sequence rules embrace all nucleotide

sequences with ten or more bases and all amino acid sequences with four or more amino acids. Said sequences must be disclosed in a sequence listing and identified by a specific SEQ ID NO: (MPEP 2421.02). 37 CFR 1.821(d) requires the use of the assigned sequence identifier number in all instances where the description or claims of a patent application discuss sequences, regardless of whether a given sequence is also embedded in the text of the description or claims of an application. Applicant is required to check the disclosure completely and to make corrections to identify all of the sequences disclosed therein by sequence identifier numbers.

Abstract

The abstract is objected to because it is a single, run-on sentence.

Specification-Objections

The specification is objected to for disclosing sequences that are not identified by a sequence identifier number (SEQ ID NO:). Applicant is required to check the disclosure completely and to make corrections to identify all of the sequences disclosed therein by sequence identifier numbers.

The specification is objected to for having a large blank space on page 33.

The specification is objected to for having an incomplete/improper listing of the figure legends. In addition, the listing of the figure legends should be located between the summary and the detailed description sections.

Claims-Objections

Claims 9 and 10 are objected to for reciting non-elected subject matter.

Claim Rejections - 35 USC § 112-Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5, 9, and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for the following reasons.

Claim 1 is indefinite because part (d) is a multiply dependent phrase dependent from the multiply dependent phrase of part (c). Claims 2-5, 9, and 10, as dependent from Claim 1, are indefinite for the same reasons.

Claim 1 is indefinite in the recitation of "functionally analogous to the polynucleotide sequence of a) through c)". It is unclear whether the recited polynucleotide is meant to be functionally analogous to any one of a) through c) or all of a) through c). Claims 2-5, 9, and 10, as dependent from Claim 1, are indefinite for the same reasons.

For Claim 1(b) and (d), the term "functionally analogous" renders the claim indefinite. Neither the claim nor the specification define which functions are encompassed. Claims 2-5, 9, and 10, as dependent from Claim 1, are indefinite for the same reasons.

Claim 1(a) recites "a nucleic acid molecule comprising a polynucleotide sequence of SEQ ID NO: 1". Said recitation encompasses a nucleic acid molecule comprising as few as two contiguous nucleotides of SEQ ID NO: 1. If Applicants wish to claim a nucleic acid molecule comprising SEQ ID NO: 1, the above phrase should be amended to "a nucleic acid molecule comprising the polynucleotide sequence of SEQ ID NO: 1". Claims 2-5, 9, and 10, as dependent from Claim 1, are indefinite for the same reasons.

Claims 2, 4, 9, and 10 are rendered indefinite by improper antecedent usage. For Claims 2, line 3, "a polynucleotide sequence as specified under a)" should be amended to "the polynucleotide sequence as specified under a)". In each of Claims 4, 9, and 10, "a nucleic acid molecule according to Claim..." should be amended to "the nucleic acid molecule according to Claim...". Claim 5, as dependent from Claim 4, is indefinite for the same reasons.

Claim Rejections - 35 USC § 112-First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Enablement

Claims 1-5, 9, and 10 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the polynucleotide of SEQ ID NO: 1, which encodes the renal AKAP of SEQ ID NO: 2, does not reasonably provide enablement for any polynucleotide that is functionally analogous to SEQ ID NO: 1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

In regards to this enablement rejection, the application disclosure and claims are compared per the factors indicated in the decision In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). These factors are considered when determining whether there is sufficient evidence to support a description that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is undue. The factors include but are not limited to: (1) the nature of the invention; (2) the breath of the claims; (3) the predictability or

unpredictability of the art; (4) the amount of direction or guidance presented; (5) the presence or absence of working examples; (6) the quantity of experimentation necessary; (7) the relative skill of those skilled in the art. Each factor is here addressed on the basis of a comparison of the disclosure, the claims, and the state of the prior art in the assessment of undue experimentation.

Claims 1, 3-5, 9, and 10 are so broad as to encompass any polynucleotide that is functionally analogous to SEQ ID NO: 1. Claim 2 is so broad as to encompass any polynucleotide functionally analogous to SEQ ID NO: 1 and having at least 80% homology to SEQ ID NO: 1. The scope of each of these claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of polynucleotides broadly encompassed by the claim. Since the amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the protein's structure relates to its function. However, in this case the disclosure is limited to the amino acid sequence of SEQ ID NO: 2 and the nucleotide sequence of SEQ ID NO: 1.

While recombinant and mutagenesis techniques are known, it is not routine in the art to screen for multiple substitutions or multiple modifications, as encompassed by the instant claims. Furthermore, the positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any protein and the results of such modifications are unpredictable (Galye et al, 1993;

Whisstock et al, 2003). In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple substitutions.

The specification does not support the broad scope of Claims 1, 3-5, 9, and 10, which encompasses all polynucleotide sequences that are functionally analogous to SEQ ID NO: 1. The specification also does not support the broad scope of Claim 2, which encompasses all polynucleotide sequences functionally analogous to SEQ ID NO: 1 and having at least 80% homology to SEQ ID NO: 1. The specification does not support the broad scope of Claims 1-5, 9, and 10 because the specification does not establish: (A) the function of all recited polynucleotides; (B) regions of the polynucleotide and/or encoded protein structure which may be modified without affecting the desired activity; (C) the general tolerance of the desired activity to modification and extent of such tolerance; (D) a rational and predictable scheme for modifying any residues with an expectation of obtaining the desired biological function; and (E) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any number of polynucleotides with an enormous number of modifications of the polynucleotide of SEQ ID NO: 1. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of the identity of sequences having the desired biological characteristics is unpredictable and the experimentation left to those skilled in

the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Written Description

Claims 1-5, 9, and 10 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the Inventors, at the time the application was filed, had possession of the claimed invention. These claims are directed to a genus of polynucleotide molecules having any number of modifications of the polynucleotide of SEQ ID NO: 1. The specification does not contain any disclosure of the function of all said polynucleotides. The genus of polynucleotide that comprise these above nucleic acid molecules is a large variable genus with the potentiality of encoding many different proteins. Therefore, many functionally unrelated polynucleotides are encompassed within the scope of these claims, including partial DNA sequences. The specification discloses the function of only a single species of the claimed genus, which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed. Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claims 1, 3-5, 9, and 10 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed,

had possession of the claimed invention. These claims are directed to a genus of polynucleotides that are "functionally analgous" to SEQ ID NO: 1. The specification teaches the structure of only a single representative species of such polynucleotides. Moreover, the specification fails to describe any other representative species by any identifying characteristics or properties other than being the functionality analogous to SEQ ID NO: 1. Given this lack of description of representative species encompassed by the genus of the claim, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-5, 9, and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Trotter et al, 1999. Trotter et al teach a polynucleotide that has 69% homology to SEQ ID NO: 1. Said polynucleotide encodes a protein kinase A anchor protein (Fig 4). Trotter et al further teach their polynucleotide in a pharmaceutical composition and in a kit (pg 1482; parg 11). Therefore, Claims 1, 3-5, 9, and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Trotter et al, 1999.

Allowable Subject Matter

No claims are allowable.

Final Comments

To insure that each document is properly filed in the electronic file wrapper, it is requested that each of amendments to the specification, amendments to the claims, Applicants' remarks, requests for extension of time, and any other distinct papers be submitted on separate pages.

It is also requested that Applicants identify support, within the original application, for any amendments to the claims and specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan L. Swope whose telephone number is 571-272-0943. The examiner can normally be reached on M-F; 9:30-7 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published application may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on the access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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SHERIDAN SWOPE, PH.D.
PRIMARY EXAMINER